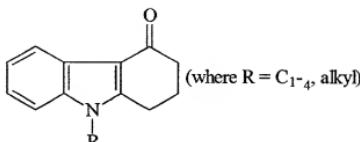


WHAT IS CLAIMED IS:

1. Ondansetron hydrochloride dihydrate having a purity of at least 99.0%.
2. Ondansetron hydrochloride dihydrate having a purity of at least 99.5%.
- 5 3. Ondansetron hydrochloride dihydrate having a purity of at least 99.9%.
4. A process for preparing dimethylamino-methyl-carbazolone comprising the steps of:

10 a) preparing a solution of methyl-carbazolone having the formula:



- 15 b) heating the solution in the presence of dimethylamine hydrochloride and paraformaldehyde;
- c) basifying the solution to form a precipitate;
- d) separating the precipitate from the solution;
- e) drying the precipitate.

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- 5 The process according to claim 4, wherein R is methyl.
- 25 6. The process according to claim 4, wherein the heating step is performed at a temperature of about 70°C to about 100°C.
7. The process according to claim 4, wherein the heating step is performed at a temperature of about 80°C to about 90°C.
- 30 8. The process according to claim 4, wherein the heating step is performed for about 6 to about 24 hours.
- 35 9. The process according to claim 4, wherein the heating step is performed for about 6 to about 12 hours.

10. The process according to claim 4, wherein the heating step is performed in acetic acid.

5 11. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and paraformaldehyde.

10 12. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.

15 13. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and formaldehyde.

14. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.

20 15. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 4 to about 6 volumes of acetic acid.

25 16. The process according to claim 4, wherein about one equivalent methylcarbazolone is heated in the presence of about 4 volumes of acetic acid.

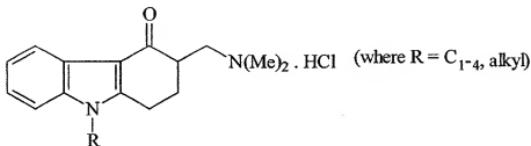
17. The process according to claim 4, wherein the solution of methylcarbazolone is basified by about 45% sodium hydroxide.

30 18. The process according to claim 17, wherein the solution is basified to a pH of about 13 to about 14.

19. The process according to claim 17 or 18, wherein the basifying step is performed in the presence of 10% celite.

20. A process for preparing ondansetron base, comprising the steps of:

5 a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



- b) heating the solution;
- c) removing a precipitate containing ondasetron base from the solution;
- d) washing the precipitate;
- e) drying precipitate to obtain ondansetron base.

21. The process according to claim 20, wherein the solution is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

22. The process according to claim 20, wherein the solution is prepared by adding about 5 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

23. The process according to claim 20, wherein the solution is prepared in the presence of 10% celite.

24. The process according to claim 20, further comprising the step of: recrystallizing ondansetron base.

25. The process according to claim 24, wherein the recrystallizing step is

performed in the presence of activated carbon and methanol.

26. A process of preparing pure ondansetron hydrochloride dihydrate comprising the steps of:

5 a) preparing a solution of ondansetron base;
b) acidifying the solution with hydrogen chloride to form a precipitate;
c) washing the precipitate; and
d) crystallizing pure ondansetron hydrochloride dihydrate.

10 27. The process according to claim 26 wherein about 3 to about 7 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.

15 28. The process according to claim 26 wherein about 5 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.

20 29. The process according to claim 26 wherein about 1.0 to about 1.4 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.

25 30. The process according to claim 26 wherein about 1.1 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.

30 31. The process of claims 29 or 30, wherein the solution is acidified to a pH about 1 to about 4.

30 32. The process of claims 29 or 30, wherein the solution is acidified to a pH about 3.

30 33. The process according to claim 26, wherein the precipitate is washed with about 5 to about 15 ml of isopropanol.

34. The process according to claim 26, wherein the precipitate is washed with about 10 ml of isopropanol.

5 35. The process according to claim 26, wherein the crystallizing step is achieved by adding about 3 to about 5 volumes of water to induce crystallization.

10 36. The process according to claim 26, wherein the crystallizing step is achieved by adding about 4 volumes of water to induce crystallization.

37. The process according to claim 26, wherein the crystallization step is repeated two times.

15 38. The process according to claim 26, wherein the crystallizing step is achieved in the presence of activated carbon.

39. The process according to claim 36, wherein the activated carbon is selected from the group consisting of SX-2, CA-1, CXV and SX-1.

20 40. The process according to claim 39, wherein the activated carbon is about 5 to about 15% SX-1.

41. The process according to claim 39, wherein the activated carbon is about 5 to about 10% SX-1.

25 42. Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%.

30 43. Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate have a purity of at least about 99.5%.

44. Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%.

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45. A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%.

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46. A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5%.

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47. A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%.

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